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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.            | CONFIRMATION NO. |
|---|-------------|----------------------|--------------------------------|------------------|
| 10/624,066  | 07/21/2003  | Wes Johnson          | 1842-0018                      | 5163             |
| 7590  | 10/28/2005  |                      |                                |                  |
| Michael D. Beck<br>Maginot, Moore & Bowman<br>Bank One Center/Tower<br>111 Monument Circle, Suite 3000<br>Indianapolis, IN 46204-5115 |             |                      | EXAMINER<br>SHAFFER, RICHARD R |                  |
|   |             |                      | ART UNIT<br>3733               | PAPER NUMBER     |
| DATE MAILED: 10/28/2005   |             |                      |                                |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

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|                              |                                       |                                       |  |
|------------------------------|---------------------------------------|---------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/624,066  | <b>Applicant(s)</b><br>JOHNSON ET AL. |  |
|                              | <b>Examiner</b><br>Richard R. Shaffer | <b>Art Unit</b><br>3733               |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 September 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 98-200 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 98-200 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 98-116, drawn to a method, classified in class 128, subclass 898.
- II. Claims 117-129, drawn to an apparatus, classified in class 606, subclass 228.
- III. Claims 130-162, drawn to an apparatus, classified in class 606, subclass 90.
- IV. Claims 163-164, drawn to a kit, classified in class 606, subclass 90.
- V. Claims 165-178, drawn to a method, classified in class 606, subclass 198.
- VI. Claims 179-190, drawn to an apparatus, classified in class 606, subclass 90.
- VII. Claims 191-200, drawn to an apparatus, classified in class 606, subclass 90.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions, and different effects. Invention I is directed towards a method of distracting two tissue surfaces with a plurality of elements. This could be as simple as a surgeon

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uses his/her own hands to pull tissue apart. Invention **V** at least claims bone tissue for separation and retention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Inventions **I** in regard to **II**, **III**, **IV**, **VI**, and **VII** are as process and apparatuses for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, none of the apparatuses claimed are required to distract tissue with a plurality of elements.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Inventions **V** in regard to **II**, **III**, **IV**, **VI**, and **VII** are related as process and apparatuses for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the method can again be performed by hand and not requiring the apparatus for distraction, and could use a balloon catheter for essentially expanding unidirectionally (such as with a doughnut balloon) within an intramedullary canal or in spinal body.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Inventions **II, III, IV, VI, and VII** are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions can all be interpreted for use in other instances, examples being sutures, knee distractors, stacking books to elevate a limb, etc. For example, there is no structure that differentiates the kit from that of a person holding two books up and separating ones arm from their chest.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct set of species of wafer, wafer inserter, wafer inserter tip, mandrel, and track/channel of the claimed invention with a representative figure of each:

**Wafer:**

|              |                  |            |                  |             |                  |              |                  |
|--------------|------------------|------------|------------------|-------------|------------------|--------------|------------------|
| <b>I:</b>    | <b>Figure 3</b>  | <b>II:</b> | <b>Figure 4</b>  | <b>III:</b> | <b>Figure 5</b>  | <b>IV:</b>   | <b>Figure 6</b>  |
| <b>V:</b>    | <b>Figure 8</b>  | <b>VI:</b> | <b>Figure 10</b> | <b>VII:</b> | <b>Figure 12</b> | <b>VIII:</b> | <b>Figure 14</b> |
| <b>IX:</b>   | <b>Figure 16</b> | <b>X:</b>  | <b>Figure 18</b> | <b>XI:</b>  | <b>Figure 20</b> | <b>XII:</b>  | <b>Figure 22</b> |
| <b>XIII:</b> | <b>Figure 24</b> |            |                  |             |                  |              |                  |

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**Wafer Inserter:**

**I: Figure 29    II: Figure 34    III: Figure 46    IV: Figure 49**

**Wafer Inserter Tip:**

**I: Figure 38    II: Figure 40    III: Figure 41**

**Mandrel:**

**I: Figure 54    II: Figure 55**

**Track/Channel:**

**I: Figure 52    II: Figure 56    III: Figure 578**

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 117, 130, 163, 179, and 191 appear generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard R. Shaffer whose telephone number is 571-272-8683. The examiner can normally be reached on 7-5 (Mon-Fri, every other Fri off).

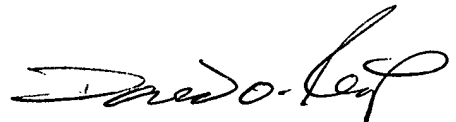
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Richard Shaffer  
10/21/2005



PRIMARY EXAMINER

10/25/05